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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION *IN LIMINE* NO. 1 TO EXCLUDE EVIDENCE OF RECOVERY® FILTER COMPLICATIONS AND OTHER COMPLICATIONS THAT ARE NOT SUBSTANTIALLY SIMILAR TO THE INCIDENT AT ISSUE

(Assigned to the Honorable David G. Campbell)

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Bard moves *in limine* to exclude evidence of other incidents and complications involving other Bard IVC filters, including the Recovery® Filter, and to require Plaintiffs to prove, outside of the presence of the jury, that another incident or complication is substantially similar to the alleged incident at issue in this case.[1] In support of this Motion, Bard respectfully shows the Court as follows:

INTRODUCTION

The product at issue in this case is the Bard G2® Filter. Plaintiff alleges that the G2 Filter implanted in her in June 2007 tilted, caudally migrated, perforated her IVC, fractured, and that fractured portions of the device embolized to other parts of her body, allegedly causing her injuries. Given those factual allegations, Plaintiff's legal claims turn on whether the G2 Filter implanted in her was defectively or negligently designed, and whether Bard provided adequate warnings to her implanting physician.

Ignoring the proper scope of the issues in this case, Plaintiff has made clear that she intends to inflame the jury by turning this G2 Filter case into a referendum on an entirely different product: Bard's Recovery Filter. As "fuel" for that effort, Plaintiff intends to introduce extensive testimony and evidence about reports of the Recovery Filter fracturing and a small number of reports of the Recovery Filter allegedly migrating to a patient's heart, resulting in patient death. In an effort to "stoke the flame" of prejudice, Plaintiff intends to offer extensive testimony and evidence about Bard's efforts to investigate, analyze, and respond to these reports of Recovery Filter fracture and migration. Plaintiff intends to do all of this, despite that this case does ***not*** involve the Recovery Filter, and does ***not*** involve a migration of the G2 Filter (much less a Recovery Filter) to her heart.

While the Court previously ruled that "Plaintiff has shown 'substantial similarity' between the Recovery and G2 Filters" as one basis for denying summary judgment on the punitive damages claim, Doc. 8874 at 21, respectfully, this issue was not significantly briefed outside of the limited summary judgment context on Plaintiff's punitive damages claim. Indeed, Plaintiff made no mention of the standard whatsoever in her Response. *See*

[1] Counsel for Defendants conferred with counsel for Plaintiffs and this motion is opposed.

Doc. 8163. Moreover, Bard's Reply mentioned the point only in a cursory fashion, and did not address the vast majority of authorities on the issue. *See* Doc. 8574. Bard respectfully submits that this question warrants more detailed briefing, as it presents the fundamental issue in this case. Specifically, the Court should determine whether the jury will be asked to analyze the questions truly at issue (alleged defects in the G2 Filter and any causal link with Plaintiff's alleged injury), or whether Plaintiff will be permitted to broaden this trial – beyond the legal issues at play – into a broad-ranging referendum on a different device: the Recovery Filter. Plaintiff should not be permitted to do so here.

FACTUAL BACKGROUND

In June 2007, Plaintiff received Bard's second generation retrievable IVC filter, called the G2 Filter. Plaintiff's G2 Filter allegedly tilted, caudally migrated, perforated, fractured, and a fractured strut embolized to Plaintiff's heart. Plaintiff allegedly experienced a "caudal" migration, movement of her filter approximately 3cm down towards her feet, ***not*** a "cephalad" or "cranial" migration, involving movement of the filter up towards her heart or lungs, which can be fatal.[2]

More than four years before Plaintiff received the G2 Filter, FDA cleared Bard's first-generation retrievable IVC filter, called the Recovery Filter. The Recovery Filter was commercially marketed from the beginning of 2003 until the fall of 2005. During that time, Bard monitored the performance of the Recovery Filter, analyzed the adverse events that were reported by doctors and others to the company, and reported the events to FDA. These adverse events included reports of Recovery Filter fracture and migration, including reports of migration of the entire Recovery Filter to a patient's heart, resulting in death.

As part of its post-market surveillance of the Recovery Filter, Bard formed internal teams (Product Assessment Teams) to study and analyze the adverse events reported

[2] Caudal migration is entirely different than cephalad migration and is often asymptomatic and clinically insignificant. *See* Christos Athanasoulis, et al., *Inferior Vena Caval Filters: Review of a 26-year Single-Center Clinical Experience*, Radiology 2000; 126:54-66, 63-64 ("We do not consider caudal migrations to be major complications. Caudal migrations are clinically relevant only when the devices move to an iliac vein."); *Cf.* Charles Owens, et al., *Intracardiac Migration of Inferior Vena Cava Filters*, Chest 2009; 136:877-887 (discussing cephalad migrations to the heart, some of which resulted in death).

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about the Recovery Filter. Bard properly documented its work, analyses, and investigations of the Recovery Filter through reports, Remedial Action Plans, and Health Hazard Evaluations. Bard also communicated with FDA and physicians about the Recovery Filter. Those efforts, complaints, investigations, and communications were undertaken long before the G2 Filter was on the market. As such, evidence of Recovery Filter complications has absolutely no relevance to the issues in this case.

In late 2005, Bard introduced the G2 Filter to the market. Based on clinical experience with the Recovery Filter, Bard made several significant changes to the G2 Filter: the filter hook wire diameter was increased, the filter leg span was increased, the filter arm length was increased, the filter arm tips were curved, the curvature radius of the filter arms at the sleeve were increased, and the spline was modified to accommodate the other dimensional changes. FDA cleared the G2 Filter for permanent use in August 2005, and as a retrievable device in January 2008. In September 2005, Bard ceased selling the Recovery Filter after it introduced the G2 Filter, more than a year and a half before the G2 Filter was ever implanted in Plaintiff.

As Plaintiff conceded in other briefing submitted in this case, one of Bard's goals in developing the G2 Filter was to reduce the number of incidents of filter fracture and migration that Bard had observed with the Recovery Filter. *See* Doc. 7950 at ¶ 63. Indeed, Bard made the dimensional changes above to the design of the Recovery when developing the G2 Filter aimed specifically at improving fracture and migration resistance. *See id.* at ¶ 313. As a result, whether the Recovery Filter fractures or migrates at a percentage that is relatively higher than other devices (which is one of the arguments Plaintiff intends to make), or whether Bard warned physicians of the relative risks of the Recovery Filter (which, again, is one of the arguments Plaintiff intends to make), has absolutely no bearing on whether a later generation filter that Plaintiff actually received -- the G2 Filter, which was intended to and in fact did address concerns about filter fracture and migration[3] -- was somehow defective and caused Plaintiff's injuries.

[3] Plaintiff's own expert cites failure rate data that demonstrates the G2 Filter experienced

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ARGUMENT AND CITATION OF AUTHORITY

A. Evidence of Other Incidents Is Admissible Only if Plaintiff Carries Her Burden of Proving That the Evidence is Substantially Similar to Her Case

It is fundamental that all evidence must be relevant to be admissible. Fed. R. Evid. 402. "Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. Evidence of other incidents or other complications is relevant and admissible ***only if*** such other incidents or other complications are "substantially similar" to the case at hand. *Cooper v. Firestone Tire & Rubber Co.*, 945 F.2d 1103, 1105 (9th Cir. 1991).[4] The reasons courts exclude dissimilar evidence is because of the recognized potential for "substantial prejudice" created by such evidence, *Tran v. Toyota Motor Corp.*, 420 F.3d 1310, 1316 (11th Cir. 2005), and the likelihood that the "jury could easily be confused or misled into imposing liability on the mere basis of what *could* have happened rather than what *did* happen." *See Bauerlein v. Equity Residential Properties Mgmt. Corp.*, No. CIV 04-1904 PHXSMM, 2007 WL 1546101, at *1 (D. Ariz. May 24, 2007) (granting motion *in limine* excluding evidence of other deaths involving defendant's mini-blinds products that occurred under different circumstances).

Plaintiff has the burden of proving substantial similarity "outside the presence of the jury." *Pau v. Yosemite Park & Curry Co.*, 928 F.2d 880, 889 (9th Cir. 1991). To carry

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a lower incidence of fracture and migration over the predicate Recovery Filter. *See* Expert Report of Rebecca Betensky (Doc. 7289 at Ex. A; Redacted copy at Doc. 8118-1), at 8-9.

[4] "Admission of other similar accidents or occurrences is governed by the federal substantial similarity doctrine and not state law." *Reid v. BMW of N. Am.*, 464 F. Supp. 2d 1267, 1271 (N.D. Ga. 2006); *Colp v. Ford Motor Co.*, 630 S.E.2d 886, 890 (Ga. Ct. App. 2006); *see, e.g.*, *W. Recreational Vehicles, Inc. v. Swift Adhesives, Inc.*, 23 F.3d 1547, 1555 (9th Cir. 1994) (explaining "general rule in federal courts" within the Ninth Circuit); *Heath v. Suzuki Motor Corp.*, 126 F.3d 1391, 1396 (11th Cir. 1997) (holding FRE, not Georgia law, govern the admissibility of similar transaction evidence in products liability action in diversity case); *accord In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, No. 3:07-CV-00101, 2010 WL 1962943, at *1 (M.D. Ga. May 14, 2010) (applying FRE instead of Georgia law). This Court applies the law of the Ninth Circuit on issues of federal law. *See* Doc. 8872 at 7. Regardless, both bodies of law require exclusion here of any incidents or complications for which Plaintiff fails to demonstrate substantial similarity. *St John v. Toyota Motor Corp.*, No. 8:10ML02151 JVS FMOX, 2013 WL 5775081, at *5 (C.D. Cal. Oct. 11, 2013) ("The Ninth Circuit has much the same standard" as that under Georgia law).

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this burden, Plaintiff must establish concrete and detailed facts to prove substantial similarity of each proffered incident. Cursory factual accounts and/or superficial similarities are not enough to prove substantial similarity. *See, e.g.*, *Nachtsheim v. Beech Aircraft Corp.*, 847 F.2d 1261, 1269 (7th Cir. 1988) ("[T]oo few *established facts* about the [prior] accident" to make comparison) (emphasis original); *Ponder v. Warren Tool Corp.*, 834 F.2d 1553, 1560 (10th Cir. 1987) (mere "superficial factual similarity between the two accidents" insufficient). "The district court must be apprised of the specific facts of previous accidents in order to make a reasoned determination as to whether the prior accidents are 'substantially similar.' Absent such a foundation, it is impossible [to do so]." *Barker v. Deere & Co.*, 60 F.3d 158, 163 (3d Cir. 1995).[5] Because "this requires a detailed consideration of each [incident]," one MDL court in this circuit recently limited the plaintiffs to presentation of only ten other incidents at trial and ordered plaintiffs to submit detailed briefing demonstrating substantial similarity through excerpts from relevant expert reports, depositions, and other data sources. *St John*, 2013 WL 5775081, at *5.

Federal courts in the Ninth Circuit and elsewhere have routinely excluded evidence of other incidents or complications where such evidence is not substantially similar to the case being tried because it involves ***different models of products***, *Daniel v. Coleman Co. Inc.*, 599 F.3d 1045, 1048 (9th Cir. 2010) (affirming exclusion of evidence of accidents caused by defendant's other models of heaters due to their dissimilarities in size, intended use, and warning language), ***different alleged injuries and complications***, *see Ramirez v. E.I Dupont de Nemours & Co.*, No. 8:09-CV-321-T-33TBM, 2010 WL 3467655, at *2 (M.D. Fla. Sept. 1, 2010) (excluding evidence of other claims of injury where, *inter alia*, the evidence involved different complications and different injuries), ***different parts of the same model of product***, *see Hamatie v. Louisville Ladder, Inc.*, No. 6:06-CV-817-ORL-18, 2007 WL 7626033, at *1 (M.D. Fla. Oct. 24, 2007) (excluding evidence of prior accidents involving the same model of ladder at issue, where the prior

[5] Nor can Plaintiff "improperly shift the burden to the Court" to review cursory evidence to find "any support for Plaintiff's claim of substantial similarity." *Steede v. Gen. Motors, LLC*, No. 11-2351-STA-DKV, 2013 WL 142484, at *9 (W.D. Tenn. Jan. 11, 2013).

claims did not involve alleged "separation of the base and fly sections" of the ladder), individuals with ***different medical courses***, *see id*., and ***different conditions giving rise to the accident***. *See Jaramillo v. Ford Motor Co*., 116 F. App'x 76, 78–79 (9th Cir. 2004) (reversing and remanding for new trial where comparative accident statistics were not "based on accidents that occurred under circumstances similar to [plaintiff's] accident").

Thus, in light of the authorities stated above, Plaintiff should be permitted to attempt to introduce evidence of other incidents or complications only after she satisfies her burden of proving -- outside of the presence of the jury -- that such other incidents or complications are substantially similar to her alleged complications with her G2 Filter.

B. Recovery Filter Complications Involving Cephalad Migration Are Not Substantially Similar to Plaintiff's Alleged Complications Involving a G2 Filter Caudal Migration and Fractured Strut Embolization

Plaintiff has already injected in this case evidence of irrelevant, dissimilar incidents involving Recovery Filter complications, in particular Recovery Filter cephalad migrations of the entire filter to patients' hearts, and Bard's analyses and investigations into such incidents. *See* Doc. 8163 at 4. These complications are not substantially similar to Plaintiff's alleged G2 Filter caudal migration and embolization of a fractured strut (***not*** the entire filter) to her heart. The following table [6] illustrates some of the main dissimilarities between these incidents:

	Recovery® Filter Cephalad Migration of Entire Filter to Heart	**Plaintiff's Alleged G2® Filter Caudal Migration and Embolization of Fractured Strut to Heart**
Different models of products	Recovery® Filter	G2® Filter
Different alleged complications	Cephalad Migration	Caudal Migration/Embolization of fractured strut
Different alleged injuries	Emergency open heart surgery and/or patient death	Non-emergent percutaneous procedure to remove filter/Non-emergent, "minimally invasive," surgical procedure to remove fractured strut from heart
Different alleged	Alleged inadequate	Shape and geometry of the G2 Filter

[6] This Table is for illustrative purposes. Bard does not intend to represent that all reports of Recovery Filter migrations to a patient's heart follow these precise parameters. Regardless, Plaintiff has the burden to prove substantial similarity of these incidents to her case. *See Cooper*, 945 F.2d at 1105. It is not Bard's burden to prove dissimilarity.

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defects	radial strength and/or anchoring hooks	makes it unstable
Different physiological forces potentially causing the complication	Filter dislodgment and migration potentially due to large clot burdens overloading the filter	Fracture allegedly caused by stresses on device following tilt, caudal migration, and/or perforation allegedly caused by normal physiological forces

As illustrated above, incidents of Recovery Filter cephalad migration of the entire filter to a patient's heart are not substantially similar to Plaintiff's G2 Filter caudal migration and strut embolization. The G2 Filter was specifically designed to address and improve upon the clinical experience with the Recovery Filter, including cephalad migration resistance. So, by their very nature, the circumstances surrounding adverse events involving a different filter and different filter complications cannot be substantially similar to Plaintiff's alleged complications. Thus, evidence of these dissimilar complications is simply not relevant because it does not tend to prove or disprove the disputed facts of consequence in this action, i.e., whether the G2 Filter implanted in Plaintiff was defective and whether any alleged defect caused her alleged injuries.

For these reasons, the Court should exclude as irrelevant evidence of Recovery Filter complications, including, in particular, evidence concerning Recovery Filter migrations to patients' hearts.

C. Evidence Of Recovery Filter Complications Is Inadmissible Under Rule 403

Plaintiff seeks to introduce at trial evidence of Recovery Filter cephalad migrations to patients' hearts resulting in patient death. Here, Plaintiff survived her fracture and strut embolization, so this evidence concerning complications resulting in patient death is not substantially similar to Plaintiff's alleged complication. Such irrelevant and inflammatory evidence is precisely the type of evidence that can lead to "substantial prejudice" to Bard and that can "confuse or mislead the jury." *Tran*, 420 F.3d at 1316; Fed. R. Evid. 403.

The probative value of any evidence in this case about complications reported through adverse events and investigation and analysis of the Recovery Filter is slight, if any, given the difference of the filter models in question, the timing of their development, and the date of the implant of the filter at issue. Any probative value of such evidence,

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especially those resulting in death, is also greatly outweighed by the unfair prejudice, misleading of the jury, confusion of the issues, and consumption of time that the admission of such evidence would cause. Put simply, this evidence is inadmissible under Rule 403. *See Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1502 (11th Cir. 1985) (Admitting evidence of the allegedly similar incidents may have "an undue tendency to suggest a decision on an improper basis"); *Bauerlein*, 2007 WL 1546101, at *1 (excluding evidence of other incidents involving death under FRE 403).

If Plaintiff is allowed to introduce evidence concerning the reported adverse events with the Recovery Filter and Bard's analysis and investigation of those incidents, Bard will necessarily have to introduce (1) its own evidence of the reasons that caused Bard to design the Recovery Filter the way it did, (2) evidence of the information and technology available when the Recovery Filter was designed, (3) evidence of the information and technology available when the G2 Filter was designed, (4) why and how Bard addressed the adverse events reported about the Recovery Filter, and (5) the extensive analysis, investigation, and reports it performed regarding the investigations it undertook regarding the Recovery Filter. This would inevitably result in a trial-within-a-trial on the development of the Recovery Filter and its performance in the marketplace (all of which took place years before a different filter was implanted in Plaintiff).

This trial-within-a-trial would waste significant judicial resources and prevent the parties from trying the issues presented by this particular case. It is for these reasons that courts routinely guard against presentation of evidence on collateral and irrelevant matters. *See Olson v. Ford Motor Co.*, 481 F.3d 619, 624 (8th Cir. 2007) ("No judge wants to see one trial turn into several, especially when the one trial presents complex issues with which the jury may already be struggling."). Ultimately, admission of the evidence regarding other incidents and complications involving the Recovery Filter will bury the Court and jury under an avalanche of collateral questions and competing arguments involving filters and circumstances not at issue in this case, thus resulting in unavoidable confusion, as well as adding substantially to the length of the trial.

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D. Evidence Of Recovery Filter Complications Is Not Relevant to Prove "Notice"

Plaintiff will likely respond to this Motion by arguing that evidence regarding Recovery Filter complications is somehow relevant to prove "notice." This argument is erroneous. First, Plaintiff intends to use Recovery Filter migration evidence (and other evidence of dissimilar incidents involving Bard's IVC filters) to prove her design defect allegations, and much more, not just to prove Bard was on "notice." Second, Bard's "notice" of the potential for a G2 Filter to move, perforate, migrate, or fracture ***is not contested by Bard in this case***. In fact, Bard's notice of these potential complications ***is precisely the reason that Bard warned about all of these complications in the G2 Filter Instructions for Use ("IFU")***. *See* G2 Filter IFU (Doc. 7457-1). Thus, where, as here, a defendant does not contest notice of the potential for a complication or injury to occur from use of its product, evidence of prior accidents has little, if any, probative value on the issue of notice. *See Thomas v. Bombardier Recreational Prods., Inc.*, No. 2:07-cv-730-FtM-29SPC, 2010 WL 4188308, at *2 (M.D. Fla. Oct. 20, 2010).

E. "Substantial Equivalence" Is Not the Same as "Substantial Similarity"

Although the Recovery Filter and the G2 Filter are "substantially equivalent" under the applicable FDA regulations, complications involving the Recovery Filter are not *per se* "substantially similar" to the G2 Filter. As noted above, a showing of "substantial similarity" under Ninth Circuit precedent requires a plaintiff to prove that "all of the incidents occurred under substantially similar circumstances." *Arnold v. Sam's Club*, 662 F. App'x 506, 506 (9th Cir. 2016). To resolve substantial similarity questions, courts often look at whether the models of products are the same, whether the alleged injuries are the same, whether the alleged complications are the same, whether the conditions giving rise to the incident were the same, as well as other factors. *See supra* Section A.

In contrast, two products can be "substantially equivalent," a distinct regulatory term-of-art, if they have the same intended use and different technological characteristics, so long as the newer product does not raise new questions of safety and effectiveness, and data demonstrates that the newer product has comparable safety and effectiveness as the

older device. *See* 21 U.S.C. § 360c(i)(1)(A). In fact, two devices can be "substantially equivalent" even if they have different technological characteristics, materials, and look very different. *See, e.g.*, "Substantially equivalent" devices attached hereto as Exhibit A.

Here, the G2 Filter has important design changes compared to the Recovery Filter. Specifically, the G2 Filter has a 25% greater leg span and 24% thicker hooks, changes which were implemented specifically to reduce the potential for cephalad migration. Additionally, the G2 Filter arms are 50% longer, the arms have curved ends, and arms emerge from the filter "sleeve" with a radiused curve, as opposed to a more acute angle. These changes were specifically implemented to make the G2 Filter more fatigue resistant. *See* Ex. A (illustration of changes). While these changes are only geometrical, they had a significant effect on the performance of the device. *See Lewy v. Remington Arms Co.*, 836 F.2d 1104, 1109 (8th Cir. 1988) (noting that even minor dimensional changes to a product, including a "change in the tolerances as small as the width of a human hair," can have a large impact on product performance, making the two products not substantially similar for purposes of deciding admissibility of prior accidents); *see also id.* (holding that trial court abused its discretion by admitting evidence of accidents involving prior model gun, where subsequent model gun was designed specifically to address problems associated with the prior model); *see also Colp*, 630 S.E.2d at 888 (applying Georgia law, affirming exclusion of other incidents involving prior model minivans, where plaintiff's subsequent model was designed specifically to address problems observed in prior model and such changes created "an appreciable difference in performance"). Indeed, Bard's clinical experience proves that the G2 Filter has improved fracture and migration rates compared to the Recovery Filter. *See* Doc. 7289 at Ex. A.

For these reasons, the mere fact that FDA found the Recovery and G2 Filters "substantially equivalent" does not *per se* mean that complications involving the Recovery Filter are "substantially similar" to complications involving the G2 Filter.

CONCLUSION

For all of these reasons, Bard respectfully requests that the Court grant its Motion.

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RESPECTFULLY SUBMITTED this 26th day of January, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of January, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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